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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,389	06/09/2005	Stanley Frinak	0256.00004	4725

7590 11/14/2007
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EXAMINER

SAIDI, AZADEH

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,389	Applicant(s) FRINAK ET AL.	
	Examiner Anita Saidi	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,10-17,21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-6,10-17,21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to the Amendment dated August 31, 2007.

The Examiner acknowledges the cancellation of claims 4, 7-9, 18-21 and 24-25 and the amendments to claims 1-3, 5-6, 10-15, 17 and 22 as well as to the drawings. Claims 1-3, 5-6, 10-17, and 22-23 are currently pending.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation “computing means for computing an algorithm....algorithm including estimating means”, as disclosed in the specification the algorithm claimed is nothing but a software program which is capable of calculating and deriving the desired values based on the collected data, however the second part of the limitation “means for estimating” is drawn to a physical system. A software/algorithm can’t include a physical system, therefore the claim is indefinite for failing to particularly point out and distinctly claim the applicant’s invention.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 17,22 and 23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 17 is drawn to an algorithm, which is saved on a computer readable medium, however upon review of the claim as a whole, there is no transformation nor does the claim produce a tangible result. Accordingly, the claim is non-statutory under 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-3, 5-6, 10-17 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,710,164 to Levin et al (Hereinafter "Levin") in view of US 4,466,804 to Hino (Hereinafter "Hino").

In reference to claims 1-3, 5-6, 10-17 and 22-23:

Levin teaches:

A method and apparatus for continuously monitoring blood pressure during hemodialysis, upon detection a decrease in patient's blood pressure the fluid extraction rate will be

reduced (Abstract of Levin). A programmed microprocessor (10 of Levin) is provided for controlling fluid extraction rate and blood pressure monitoring intervals (Col. 1, lines 61-65 of Levin), which is connected to an extracorporeal blood circuit (hemodialysis machine 16 of Levin) will automatically analyze blood pressure at variable intervals for detecting irregular blood flow and comparing the blood pressure to a standard (Abstract and Col. 1, lines 54-68 of Levin). If the patient's blood pressure remains below the systolic and/or diastolic low alarm limits, this is an indication of a potential stenotic lesion, an audible alarm is activated to call for manual intervention (Col. 2, lines 1-6 and 17-20 of Levin). The blood pressure monitor (14 of Levin), detects and estimates the intravascular blood pressure of the patient. Cabal/electronic communication which connect the display to the dialysis machine) are used as means for communication a warning when the blood pressure is off limits (Col. 4, lines 18-22 of Levin). The Microprocessor is preprogrammed with high and low blood pressure alarm limits which may be modified from an operator control panel, the microprocessor is also preprogrammed to detect deviation of blood pressure from initial readings obtained

and stored at the onset of dialysis (Col. 4, lines 45-65 of Levin).

However, Levin fails to teach that:

The Automatic blood pressure monitoring system is an extracorporeal blood flow circuit; which is used to derive the intravascular blood pressure.

Hino teach:

An extracorporeal blood circulation system including a line for withdrawing the venous blood from the patient, a reservoir for the blood withdrawn, a blood supply line for sending out the blood from the reservoir to the artery of the patient. The blood supply pump is stopped when the arterial pressure of the patient measured is above a predetermined upper limit value, while the pump is driven when the arterial pressure has lowered to a level below a lower limit value (Abstract of Hino).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used an extracorporeal blood pressure monitoring system similar to the one taught by the extracorporeal circulation device of Hino, instead of the automated blood pressure monitor of Levin, in order to stop the dialysis machine if the blood pressure decreases as monitored in the catheter, this would have yielded predictable result since both

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apparatuses are used to monitor blood pressure during blood transfusion, and for monitoring blood pressure for safety issues..

Response to Arguments

2. Applicant's arguments, see pages 6-12, filed August 31, 2007, with respect to the rejection(s) of claims 1-9, 15-16 and 17-23 under 35 U.S.C. 101, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly filed amended claims.

3. Applicant's arguments see page 8, lines 20-27, filed August 31, 2007, with respect to the rejections of claims 1-9, 15-16 and 17-23 under 35 U.S.C. 112 first paragraph have been fully considered and are persuasive. The rejection of claims has been withdrawn.

4. Applicant's arguments, see page 9, filed August 31, 2007, with respect to claims 1-9, 15-16 and 17-23 under 35 U.S.C. 112 second paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly filed amended claims.

5. Applicant's arguments, see page 10, filed August 31, 2007 with respect to the rejection(s) of claim(s) claims 1-16 and 24-25 under 35 U.S.C. 102 (b) have

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been fully considered and are persuasive. Therefore, the rejection of the claims has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amended claims as set forth above citing Levin and Hino.

6. Applicant's arguments see page 7, filed August 31, 2007, with respect to the rejections of claims 1-16 and 24-25 under 35 U.S.C. 112 sixth paragraph have been fully considered and are persuasive. The rejection of claims has been withdrawn.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 8:30 am - 7:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
11/06/2007

/Charles A. Marmor, II/
Supervisory Patent Examiner
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